C.S. A3: Observational Study Using Provider Interviews and Questionnaires

C.S. A3.1: Interviews and Questionnaires of Provider Opinions

Overview

This study will use provider interviews and written surveys to assess how a new clinical reminder system is working at 8 VAMCs. (The study is an investigator initiated research project, not a quality improvement project initiated by medical center management.)

Subjects and Sample Size

The subjects are 70 VA primary care physicians at 8 VAMCs.

Data Collection and Confidentiality

Data collected will include perceptions of barriers and facilitators to implementation of the system, provider self-efficacy, satisfaction with the system, and data about organizational structure. The provider-subjects will sign a written consent form. Data are confidential, but are not anonymous since providers are interviewed in person and data from interviews and surveys must be linked. The crosswalk file linking provider identifying data to study identification numbers will be maintained as a separate file, in a password-protected drive that is separate from the drive containing the study data. No study data will be maintained with the provider identifying data.

What type of review should this application receive and why?

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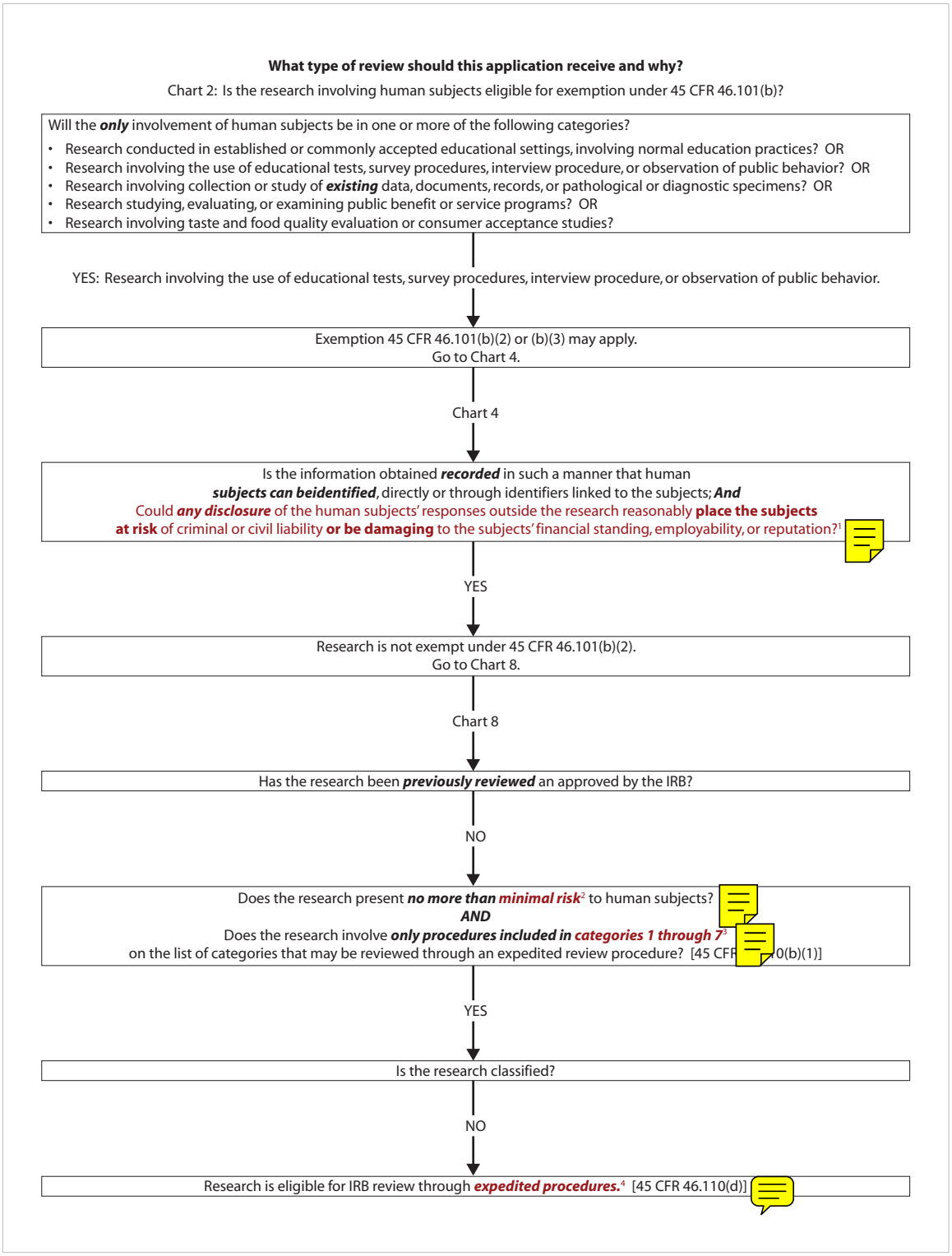
[From OHRP Web site: www.hhs.gov/ohrp/humansubjects/guidance/decisioncharts.htm]



Notes for C.S. A3.1

[1]**Definition:** There are identifiers in the study data set that can be linked to the subject. In addition, disclosure of the data, which includes employees' opinions about an aspect of their workplace, could potentially damage the subject's employability or reputation. If a participant criticized the organization, and if his/her supervisor found out, the supervisor might seek retribution of some kind.

[2]**Definition:** "Minimal risk means that the ***probability*** and ***magnitude*** of harm or discomfort anticipated in the research are not greater in and of themselves than those ***ordinarily encountered in daily life*** or during the performance of routine physical or psychological examinations or tests" (CFR 46.102(1)).

Discussion: The majority of the panel felt that the ***probability and magnitude*** of loss of confidentiality, given the safeguards described, are no greater than ***that which is encountered in daily life***—e.g., the probability of loss of confidentiality of a critical remark regarding the organization made in passing to other employees, in e-mails, in employee satisfaction surveys, etc. The small probability of loss of confidentiality is based on the assumption that the safeguards for maintaining data confidentiality by the investigators are adequate. In particular in this case, investigators need to pay close attention to how the data will not only be stored, but how the data will be reported. Because of potentially small sample sizes, it may be easy to ascribe data (comments) to a particular employee based on various characteristics of the respondent(s) included in reported findings. In addition, if the facility has a history of responding negatively to employee criticism, the magnitude of risk may be greater than average, thus requiring greater attention to reducing the risk of breach of confidentiality. In cases of concern with the procedures for maintaining confidentiality, full review by the local IRB may be desirable.

Other panel concerns centered around the types of questions included in the interviews and questionnaires. For example, if the questions addressed issues of missed diagnoses, then disclosure of the findings associated with an individual could have potential malpractice implications. In this case the magnitude of harm resulting from the loss of confidentiality is greatly increased, and full review may be warranted.

[3]**Definition:** The research involves procedures included in category 7: Research on individual or group characteristics (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. [Return to home page for full list of categories eligible for expedited review under 45 CFR 46.110(b)(1).]

[4]**Discussion:** The research is potentially eligible for expedited review under the assumptions described in the above notes from the panel discussion. A member of the IRB who understands these issues would need to review carefully the proposed research and make this determination.